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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,041	01/09/2001	John C. Reed	P-LJ 4494	6395

23601 7590 02/25/2002

CAMPBELL & FLORES LLP
4370 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122

EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/25/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/757,041

Applicant(s)
Reed et al

Examiner
Ungar

Art Unit
1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 9, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-59 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other:

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1. Claims 1-59 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

Group I. Claims 1-3 are drawn to a substantially purified mammalian CD40, CAP, classified in Class 530, subclasses 300+ and 350+.

Group II. Claims 4-6 are drawn to a reagent that binds to CAP classified in Class 530, subclasses 350+ and 387.3.

Group III. Claims 7-12 are drawn to a substantially purified nucleic acid, vector and host cell, classified in Class 536, subclass 23.1, Class 435, subclasses 253.1 and 69.1

Group IV. Claims 13-20, 22, 23, 25-27 are drawn to a method of identifying an effective agent that alters the association of CAP and a second

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molecule *in vivo* by increasing the association, classified in Class 435, subclass 4.

Group V. Claims 13-20, 22, 23, 25-27 are drawn to a method of identifying an effective agent that alters the association of CAP and a second molecule *in vivo* by decreasing the association, classified in Class 435, subclass 4.

Group VI. Claims 13-21, 23-34 are drawn to a method of identifying an effective agent that alters the association of CAP and a second molecule *in vitro* by increasing the association, classified in Class 435, subclass 4.

Group VII. Claims 13-21, 23-34 are drawn to a method of identifying an effective agent that alters the association of CAP and a second molecule *in vitro* by decreasing the association, classified in Class 435, subclass 4.

Group VIII. Claim 35 is drawn to a method of altering the association of a CAP with a second molecule, increasing association, in a cell *in vivo*, classified in Class 424, subclass 133.1.

Group IX. Claim 35 is drawn to a method of altering the association of a CAP with a second molecule, decreasing association, in a cell *in vivo*, classified in Class 424, subclass 133.1.

Group X. Claim 35 is drawn to a method of altering the association of a CAP with a second molecule, increasing association, in a cell *in vitro*, classified in Class 435, subclass 4.

Group XI. Claim 35 is drawn to a method of altering the association of a CAP with a second molecule, decreasing association, in a cell *in vitro*, classified in Class 435, subclass 4.

Group XII. Claims 36-39 are drawn to a method of modulating the function of a cell, *in vitro*, classified in Class 435, subclass 4.

Group XIII. Claims 36-39 are drawn to a method of modulating the function of a cell, *in vivo*, classified in Class 435, subclass 4.

Group XIV. Claim 40 are drawn to a method of identifying a CAP agonist which increases the level of expression of a CAP, classified in Class 435, subclass 4.

Group XV. Claims 41-42, 48, 49, 51-53 are drawn to a method of increasing the level of expression of a CAP *in vivo*, classified in Class 424, subclass 130.1.

Group XVI. Claims 41-42, 48, 49, 51-53 are drawn to a method of increasing the level of expression of a CAP *in vitro*, classified in Class 424, subclass 130.1.

Group XVII. Claim 43 are drawn to a method of identifying a CAP antagonist which increases the level of expression of a CAP, classified in Class 435, subclass 4.

Group XVIII. Claims 44-48, 50, 51-53 are drawn to a method of decreasing the level of expression of a CAP *in vivo*, classified in Class 424, subclass 130.1.

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Group XIX. Claims 44-48, 50, 51-53 are drawn to a method of decreasing the level of expression of a CAP *in vitro*, classified in Class 424, subclass 130.1.

Group XX. Claims 54-56 are drawn to a method of detecting CAP-1 protein in a test sample, classified in Class 435, subclasses 4 and 7.1.

Group XXI. Claims 57-59 are drawn to a method of detecting a CAP-1 nucleotide sequence a test sample, classified in Class 435, subclasses 4 and 6.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-III as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions IV-XXI are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups I/II/III and IV-XIX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the protein product as claimed can be used in a materially different process such as the production of an antibody. In the instant case the binding reagent product as claimed can be used in a materially

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different process such as production of an antibody or an anti-idiotypic antibody. In the instant case the nucleic acid product as claimed can be used in a materially different process such as production of the protein product.

The inventions of Groups I/II and XX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the protein product as claimed can be used in a materially different process such as the production of an antibody. In the instant case the binding reagent product as claimed can be used in a materially different process such as production of an antibody or an anti-idiotypic antibody.

The inventions of Groups III and XXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the nucleic acid product as claimed can be used in a materially different process such as production of the protein product.

The inventions of Groups I/II and XXI are not at all related because the products of Groups I/II are not used in any of the methods of Group XXI.

The inventions of Groups III and XX are not at all related because the nucleic acid product of Group III is not used in any of the methods of Group XX.

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Group II is further subject to election of a single disclosed species.

Claim 4 is generic to a plurality of disclosed patentably distinct species comprising reagents that bind to CAP which have different structures and functions wherein the agents are (a) CD40 (claim 5), (b) anti-CAP antibody.

6. Groups IV-VII are further subject to election of a single disclosed species.

Claim 13 is generic to a plurality of disclosed patentably distinct species comprising second molecules with different structures and functions wherein the second molecules is (a) CD40 (claims 15 and 30), (b) contains a TRAF domain and is not CAP-1, TRAF1 or TRAF2 (Claims 16 and 31), © contains a TRAF domain and is CAP-1 (Claims 17 and 32), (d) contains a TRAF domain and is TRAF1 (Claims 17 and 32), (e) contains a TRAF domain and is TRAF2), (f) is a nucleotide sequence (Claims 18 and 33).

7. Groups VI and VII are further subject to election of a single disclosed species.

Claim 13 is generic to a plurality of disclosed patentably distinct species comprising methods that differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success wherein the method is carried out in (a) yeast cells (Claim 24), (b) mammalian cells (Claim 23).

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8. Groups IV-VII are further subject to election of a single disclosed species.

Claim 13 is generic to a plurality of disclosed patentably distinct species comprising effective agents which differ in structure and function wherein the agents are (a) a drug (Claims 25, 29), (b) a peptide (Claims 26).

9. Groups XII-XIII are further subject to election of a single disclosed species.

Claim 36 is generic to a plurality of disclosed patentably distinct species comprising different functions within a cell wherein the functions are (a) immunoglobulin class switching (Claim 37), (b) cell proliferation (Claim 38), © apoptosis (Claim 39).

10. Groups XV, XVI, XVIII, XIX are further subject to election of a single disclosed species.

Claim 48 is generic to a plurality of disclosed patentably distinct species comprising different functions within a cell wherein the functions are (a) immunoglobulin class switching (Claim 51), (b) cell proliferation (Claim 52), © apoptosis (Claim 53).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R.

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§ 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

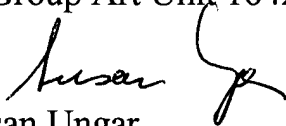
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

A handwritten signature in cursive script, appearing to read "Susan", followed by a stylized flourish or initial.

Susan Ungar
Primary Patent Examiner
February 21, 2002